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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,658	12/03/1998	GARY RUVKUN	00786/351004	7404

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EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/205,658

Applicant(s)

RUVKUN ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 April 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-5, 10-15, 23, 25 and 26.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 29.
10. ☐ Other: _____


JEFFREY FREDMAN
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because:

Claim Rejections - 35 USC § 112

1. Claims 1-5, 10-15, 23, 25 and 26 (as amended) would stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicant argues that written description rejection should be withdrawn, since claim as amended recites "C.elegans daf-18" and "human PTEN genes". However, this is not found persuasive because the scope of instant invention as claimed encompasses any and variants or homologs of C.elegans daf-18" and "human PTEN genes". At best the instant specification as filed only disclosed nucleotide sequences of SEQ ID NO: 311, which represent C.elegans daf-18 gene. Similarly, the specification as filed only teaches the amino acid sequences of SEQ ID NO: 308 (Ac:U93051), which represent phosphatase domain of human PTEN. The specification fails to disclose any and all variants (natural or non-natural) of C.elegans daf-18 and human PTEN genes. The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see *In re Shokal* 113USPQ283(CCPA1957); *Purdue Pharma L. P. vs Faulding Inc.* 56 USPQ2nd 1481 (CAFC 2000). In addition possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention *Pfaff v. Wells Electronics, Inc* 48 USPQ2d 1641, 1646 (1998). According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

2. Claims 1-5, 10-15, 23, 25 and 26 (as amended) would stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound that modulates C.elegans DAF-18 (SEQ ID NO:311) or human PTEN (Ac:U93051) expression or activity in

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C. elegans, isolated C. elegans cells, isolated mammalian cells or transgenic C.elegans, does not reasonably provide enablement for a method for identifying a candidate compound using any and all variants of C. elegans DAF-18 or human PTEN genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The applicant argues that in view of recent amendment the enablement rejection should be withdrawn. However, this is not found persuasive because the scope of invention as claimed encompasses a method of screening compounds using genetically engineered cells or transgenic C.elegans which encodes any and all variants of C.elegans daf-18 and human PTEN genes. At best the instant specification as filed only disclosed nucleotide sequences of SEQ ID NO: 311, which represent C.elegans daf-18 gene. The instant specification only teaches the amino acid sequences of SEQ ID NO: 308 (Ac:U93051), which represent phosphatase domain of human PTEN. The specification fails to disclose any and all variants of C.elegans daf-18 and human PTEN genes. Since the specification fails to disclose any and all natural and or non-natural variant of C.elegans daf-18 and human PTEN genes, it is unclear how one skill in the art would use the invention as claimed (making genetically engineered mammalian cells, C.elegans cells or transgenic C.elegans) without excessive and undue amount of experimentation. Making and testing any and all variants of a gene, especially when the gene function has been exploited in the screening of compounds that modulates a defined cellular pathway (increasing longevity or obesity) is not considered routine in the art, and without sufficient guidance to a particular allelic variant the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.